K113086

510(K) Summary as per 21 CFR 807.92(c)

JAN 13 2012

TMIC
TEXAS MEDICAL IMAGING CONSULTANTS

General Information:

A. Submitted by: Texas Medical Imaging Consultants
4027 Underwood St.
Houston, TX 77025
Tel: 713-409-3801

Contact Person: Tinsu Pan

Date Summary Prepared: 8/25/2011

B. Device Trade Name: ACQA

Classification Code: KPS

Classification Name: System, Emission Computed Tomography (per 21 CFR 892 1200)
Accessory to Emission Computed Tomography System

C. Predicate Devices:
GE Healthcare Technologies (formerly GE Medical Systems) – GE Discovery ST– K041543
GE Medical Systems -- Advantage 4D option – K032915

D. Device Description:
ACQA is a software application installed on GE Advantage Windows workstation computers which allows physicians and healthcare professionals (1) to create averaged CT images for attenuation correction of the whole body oncology or myocardial perfusion PET images, and (2) to register the averaged or helical CT images with their corresponding myocardial perfusion PET images, and save the registered CT images for attenuation correction of the myocardial perfusion PET images. Use of this system is limited to qualified, licensed healthcare providers (radiologists, nuclear cardiologists, or nuclear medicine physicians) trained in the use of nuclear medicine imaging devices.

E. Intended Use of the Device:
The ACQA system is a software on GE Advantage Windows workstation computers that allow the user to create averaged CT images for attenuation correction of the whole body or myocardial perfusion PET images, and to register CT images with myocardial perfusion PET images, and save registered CT images for attenuation correction of the myocardial perfusion PET images. The PET images corrected with the CT images of ACQA are <u>not</u> a replacement of the original PET images, and they serve as a secondary data set to assist the physician read the original PET images.

F. Comparison of Technical Characteristics to Predicate Device:
The ACQA system and its predicates, the GE DST (K041543) and the GE Advantage 4D-option (K032915) utilize the same type of data sets for analysis and data processing. The ACQA, applicable to all GE PET/CT scanners, accomplishes the tasks of registration of CT and PET, and calculation of averaged CT. The same function of ACQA is only supported on the GE PET/CT

scanners with Dimension console, and the Advantage 4D option. A summary of differences is provided in the following table.

	GE Discovery ST	GE Advantage 4D option	ACQA
Functionality	1. Attenuation correction of PET data with averaged CT data 2. Registration of CT and PET data	1. Calculation of averaged CT data with the Varian™ respiratory gating hardware	1. Attenuation correction of PET data with averaged CT data 2. Registration of CT and PET data 3. No Varian™ respiratory gating hardware is needed.
Applicable PET/CTs	GE PET/CT with Dimension console	All GE PET/CT scanners	All GE PET/CT scanners
Advantages over ACQA	Both data processing and data correction can be performed on the Dimension console	Can produce 10 phases of 4DCT images for Radiation Oncology application	Data processing on the GE Advantage Windows workstation, and attenuation correction of PET data on the PET/CT console.
ACQA Advantages over GE predicate devices	No averaged CT data is produced. The user can perform either attenuation correction by averaged CT data or registration of regular CT with PET data, and cannot use both options.	Can produce averaged CT data. However, 4DCT option is typically installed for radiation oncology, not for cardiology.	ACQA is the only software that does not require the Dimension console or 4DCT option (installation of both costs > $200k.) to compute averaged CT data for attenuation correction of the PET data and registration of the PET data with either averaged CT or helical CT data.
Large installed base of Advantage Windows workstation	Over 10,000 Advantage Windows workstations have been installed worldwide. It is very likely that a clinic/hospital which wants to use the ACQA software is already with an Advantage Windows workstation. In this case, ACQA software can be installed without any addition of hardware.		

G. Performance data: The tests with both laboratory and clinical data sets included in the submission passed the requirements and met specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Mr. Tinsu Pan
Chief Technology Officer
Texas Medical Imaging Consultants
4027 Underwood Street
HOUSTON TX 77025

Re: K113086
Trade/Device Name: ACQA System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS & JAK
Dated: October 12, 2011
Received: October 18, 2011

Dear Mr. Pan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Indications for Use Statement

The ACQA system is a software on GE Advantage Windows workstation computers that allow the user to create averaged CT images for attenuation correction of the whole body or myocardial perfusion PET images, and to register CT images with myocardial perfusion PET images, and save registered CT images for attenuation correction of myocardial perfusion PET images. The PET images corrected with the CT images of ACQA are not a replacement of the original PET images, and they serve as a secondary data set to assist the physicians read the original PET images.

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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